K080711

G. 510(k) Summary

SEP - 2 2008

G.1 Manufacturing Establishment and Contact Information

G.1.1 Manufacturer Name and Address:

Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730

G.1.2 Establishment Registration Number:

1221300

G.1.3 Name, Title, and Telephone Number of Contact:

Bryan Cowell, RAC
Regulatory Affairs Specialist
Phone: (781) 999-7300, ex. 7085
Fax: (781) 999-0614
Bryan.cowell@hologic.com

G.2 Device Identification

G.2.1 Device Trade Name:

10-year Fracture Risk Questionnaire Option for QDR X-Ray Bone Densitometers

G.2.2 Common / Usual Name:

Software option for Bone Densitometers

G.2.3 Proposed Intended Use:

Femoral neck BMD and clinical risk factors are used to estimate the patient's 10-year risk of hip fracture and 10-year risk of fracture using the World Health Organization (WHO) algorithm (FRAX™). The physician may use the 10-year percent probability of fracture, along with the physician's knowledge of patient history, and apply medical expertise and best practice clinical judgment to the obtained 10-year percent probability results to determine if therapeutic intervention is necessary.

G.3 Device Classification

Radiology

G.3.1 Classification:

Class II

G.3.2 Classification Name and Rule

Bone Densitometer: 21 CFR 892.1170

G.3.3 Classification Panel

Radiology

G.3.4 Product Code

90 KGI

G.3.5 Predicate Devices

- 510(k) No.: K963363
  Trade Name: NHANES Reference Data Software Option for Hologic QDR Series X-Ray Bone Densitometers
  SE Date: November 22, 1996
  Manufacturer: Hologic, Inc.

- 510(k) No.: K983028
  Trade Name: Estimation of Fracture Risk from BMD using Hologic QDR X-Ray Bone Densitometers
  SE Date: November 13, 1998
  Manufacturer: Hologic, Inc.

G.4 Conclusion:

The Hologic 10-year Fracture Risk Questionnaire option is substantially equivalent to the presently marketed predicate devices, the Hologic Estimation of Fracture Risk from BMD using Hologic QDR X-Ray Bone Densitometers (K983028) and the Hologic NHANES Reference Data Software Option for Hologic QDR Series X-Ray Bone Densitometers (K963363), and no new safety or efficacy questions are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

Mr. Bryan Cowell
Regulatory Affairs Specialist
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K080711
Trade/Device Name: 10-year Fracture Risk Questionnaire Option for QDR X-Ray Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: July 10, 2008
Received: July 11, 2008

Dear Mr. Cowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A.2 Indication for Use Statement

510(k) Number (if known): K080711

Device Name: 10-year Fracture Risk Questionnaire Option for QDR X-Ray Bone Densitometers

Indication for Use: Femoral neck BMD and clinical risk factors are used to estimate 10-year risk of hip fracture and 10-year risk of major osteoporotic fracture using the World Health Organization (WHO) algorithm (FRAX™) in adults. The physician may use the 10-year fracture risk, along with the physician's knowledge of patient history, and apply medical expertise and best practice clinical judgment to determine if therapeutic intervention is indicated.

Prescription Use V (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080711